



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC - 1 1997

1 4 9 0 '98 FEB 18 A 8 :02

President
Am-ion, Inc.
6565 Odell Place
Boulder, Colorado 80301-3330

Dear Sir:

This is in response to your letter of November 5, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Amrion, Inc. is making the following statements, among others, for the following products:

HealthSmart Cranberry

"... active compounds in cranberries help your body keep **harmful** bacteria from attaching to urinary tract walls."

HealthSmart Acidophilus

"High fat, high sugar diets create an ideal environment for "**unfriendly**" bacteria in the gastrointestinal tract. Don't let these harmful forms of bacteria crowd out the beneficial ones. for [sic] a healthy balance, discover the benefits of HealthSmart **Acidophilus**."

Sugars and fats can create an ideal environment for **ham-did bacteria**, which in turn can crowd out the beneficial ones needed for gastrointestinal health. For a healthy balance, discover the benefits of **Acidophilus**."

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate disease, in that they are intended to treat, prevent, or mitigate gastrointestinal disease and urinary tract disease caused by pathogenic microorganisms. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs **within** the meaning of section **201** (g)(1)(B) of the act, and that they are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10,7520 Standish Place, Rockville, Maryland 20855.

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Your submission also states that you are **making** claims of a relationship between various substances and osteoporosis for the products HealthSmart Daily Essentials, HealthSmart Calcium Carbonate, and HealthSmart Calcium& Magnesium Complex.

These statements are not statements of nutritional support subject to section 403(r)(6) of the act, but are health claims subject to section **403(r)(1)(B)** of the act. FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under section 403(r)(1)(B) of the act. Moreover, **failure** to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under section 201 (g)(1)(B) of the act because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

For the product HealthSmart Daily Essentials, for example, a claim is made that “with extra calcium, magnesium and boron, it supports bone health and helps prevent osteoporosis.” FDA has not authorized a health claim on the relationship between magnesium or boron and osteoporosis. As discussed above, this claim subjects the product to regulation as a drug under section 201 (g)(1)(B) of the act because the product is intended to prevent osteoporosis and the claim is not an authorized health claim under section **403(r)(1)(B)** of the act.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and **Enforcement** Policy
Office of Special Nutritional
Center for Food **Safety**
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Compliance Branch, HFR-SW240



November 5, 1997

NOV 18 1997

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to §403(r)(6) of the Federal Food Drug and Cosmetic Act (FDCA), 21 U.S.C. §343(r)(6).

Name of dietary supplement: HealthSmart Acidophilus

Statement(s) of
nutritional support:

Good bacteria for your colon -- good health for you. High fat, high sugar diets create an ideal environment for "unfriendly" bacteria in the gastrointestinal tract. Don't let these harmful forms of bacteria crowd out the beneficial ones, for a healthy balance. discover the benefits of HealthSmart Acidophilus.

For gastrointestinal health. Sugars and fats can create an ideal environment for harmful bacteria, which in turn can crowd out the beneficial ones needed for gastrointestinal health. For a healthy balance. discover the benefits of Acidophilus

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements] is [are] truthful and not misleading.


AMRION, INC.

55792



November 5, 1997

NOV 18 1997

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington DC 20204

NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to §403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C §343(r)(6).

Name of dietary supplement: HealthSmart Cranberry

Statement(s) of nutritional support: Natural support for urinary tract health. Research shows that active compounds in cranberries help your body keep harmful bacteria from attaching to urinary tract walls.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement(s) is/are truthful and not misleading.

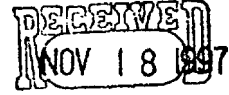
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AMRION, INC.

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November 5, 1997



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 c street, Sw
Washington, DC 20204

NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to §403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act). 21 U.S.C. §343(r)(6).

Name of dietary supplement: **HealthSmart Calcium Carbonate**

Statement(s) of
nutritional support:

Fight osteoporosis. * Nutritionally support bones for strength and density ... because inadequate calcium can contribute to porous, brittle bones and osteoporosis. *Regular exercise and a healthy diet containing adequate calcium helps women maintain good bone health and may reduce their high risk of osteoporosis later in life. Daily intake of calcium above 2,000 mg is not likely to provide any additional benefit.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading.

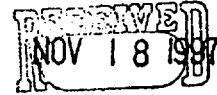
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AMRION, INC.

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November 5, 1997



Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to §403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. §343(r)(6).

Name of dietary supplement: HealthSmart Daily Essentials

Statement(s) of
nutritional support:

... specifically **targeted for** women's health concerns. With extra calcium, magnesium and **boron**, it supports bone health and helps **prevent** osteoporosis. *
*Regular exercise **and a healthy** diet containing adequate calcium helps women maintain good bone **health and may** reduce their high risk of **osteoporosis** later in **life**. Daily intake of calcium **above 2,000** mg is not **likely** to provide **any additional** benefit.

A multivitamin formula for women . . this comprehensive multivitamin helps you fill in the nutritional **gaps . . . specifically** targeted to women's health concerns. **With extra calcium, magnesium and boron, it supports bone health and helps** prevent osteoporosis.

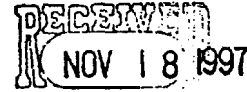
I certify that the information contained in this notice is complete and accurate, and that **we have** substantiation that the **statement[s]** is [are] **truthful** and not misleading.


AMRION, INC.

55787



November 5, 1997



Office of Special **Nutritionals** (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20205

NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

This Notification is filed pursuant to §403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. §343(r)(6).

Name of dietary supplement: **HealthSmart Calcium & Magnesium Complex**

Statement(s) of
nutritional support:

For strong healthy bones. * . . without enough calcium, your bones could become weak and brittle. In addition studies say that calcium should be taken with magnesium for even greater benefit. a blend of two important minerals for bone health. *Regular exercise and a healthy diet containing adequate calcium helps women maintain good bone health and may reduce their high risk of osteoporosis later in life. " Daily intake of calcium above 2,000 mg is not likely to provide any additional benefit.

For strong, healthy bones. Nourish strong healthy bones*. Calcium helps prevent osteoporosis and the weak, brittle bones that can result. Magnesium provides powerful overall nourishment for your bones. Together these two minerals offer super support for strong, healthy bones in a form that's easy for your body to absorb. *Regular exercise and a healthy diet containing adequate calcium helps women maintain good bone health and may reduce their high risk of osteoporosis later in life. Daily intake above 2,000 mg is not likely to provide any additional benefit.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements is [are] truthful and not misleading.


AMRION, INC.

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